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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/629,557

Applicant(s)

MILLER ET AL.

Examiner

Marianne Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 27-54 and 59-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26,55-58 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2000 and 10 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

### DETAILED ACTION

The papers filed on 1/16/01 (certificate of mailing dated 10/31/01) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

### COPY OF PAPERS ORIGINALLY FILED

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If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-24 and 55-58, Paper No. 6 is acknowledged. The traversal is on the ground(s) that the inventions as grouped are not distinct and "relate to specific aspects or applications of the generally disclosed SDAR methods." This is not found persuasive because the claims as originally written and presented are directed to different methods with significantly different preamble goals

and steps. The groups of claims are directed to analogous embodiments of SDAR, particularly in the independent claims. That is, one group of claims is not clearly a submethod completely contained within another method as written. As such, burden exists and the search for one group would not be coextensive with another. Although not argued as such, given the nature of the invention and dependency of the claims, the examiner will rejoin the claims of Group VII with the methods of Group I.

The requirement is still deemed proper and is therefore made FINAL with respect to Groups II-VI.

Claims 27-54 and 59-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

**Claims 1-26, 55-58, and new claim 65 are under consideration by the examiner.** Applicant is advised that in the response filed 1/16/02, the new claim is incorrectly numbered as 66. This has been corrected to claim 65 in accordance with 37 CFR 1.126.

### *Specification*

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code throughout the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: Claim 3 needs a period (".") following the claim number.

Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 65 recites a method where biological properties are predicted for a test compound followed by additional steps for prediction of physical or chemical properties. No basis is seen for this claim as written and none has been provided. Note that this claim is not equivalent to that in the non-elected method of Group II, exemplified by claim 27.

Claims 1- 26, 55-58, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is confusing in reciting "derived not exclusively from the assigned spectral data." The spectral data of the test compound is compared to a pattern of spectral data associated with a biological activity that appears to contain more than the training set of compounds. However, the similarities detected in the next step are only between the test compound spectra and the training set spectra. It does not appear to include comparison to this additional spectral data. This inconsistency is confusing as to what is intended. Another interpretation could be that this phrase modifies the test

compound biological activity, but this is unclear as to what would be intended. Also, does “assigned spectral data” imply calculated spectral values or a particularly chosen training set or something else?

Claim 7 is confusing in its dependency on claim 6. Claim 6 requires one type of spectral data whereas claim 7 “comprises” or can include more than one.

Claim 14 fails to further limit the subject matter of claim 1 because the nature of the invention implies that the method of claim 1 is performed on a computer and that similarities between patterns as set forth in claim 1 are detected by pattern matching. If applicant does not agree that these are implicit limitations of claim 1, then they have not described nor enabled performing the method of claim 1 in a non-computer environment nor without pattern recognition techniques. Likewise, claim 17 fails to further limit the subject matter of claim 1.

Claim 18 is directed to a computer implemented system for predicting a biological activity; however, no system components (input device, output device, computer memory) are recited. As written, it appears to be a method. It is noted that while the preamble is directed to predicting a biological activity, there are no steps for such a prediction in the body of the claim. Matching patterns is not a prediction.

Claim 56 is confusing in further defining the spectral data as experimental, calculated, and combinations thereof. This does not appear to further limit claim 21 as there do not appear to be any other ways of producing spectral data.

Claim 65 is confusing because it adds steps with respect to predicting physical and chemical properties that no longer correspond to the goal of the preamble of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-19, 21, 26, and 56-58 are rejected under 35 U.S.C. 102(a) as being anticipated by the copy of the panels from a poster authored by Beger et al. and presented at an FDA forum on December 8-9, 1998 (cited on IDS)

This poster was authored by Beger, Miller, Wilkes, and Sheehan which differs from the instant inventive entity of Miller, Beger, Lay, Wilkes, and Freeman. It is valid art under 35 USC 102(a) as it is by other and demonstrates that the invention was known or used by others in this country prior to the filing date of the instant application.

Although the preamble is directed to a computer implemented system for predicting a biological activity, no system components nor prediction steps are required.

The poster panels disclose a computer method for comparing the <sup>13</sup>C NMR spectra of compounds having a known biological activity of binding to the estrogen receptor and comparing them by cluster analysis. As such, this anticipates the steps of the claim. Pattern recognition would have been used in this analysis.

Claims 1, 3-9, 14-15, 17, 18-21, 25-26, and 55-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Bursi et al.

Bursi et al. discloses predicting biological activity for test compounds from their IR, mass, <sup>1</sup>H NMR, and <sup>13</sup>C NMR spectra as descriptors in 3D modeling. A training set of 38 progestagen compounds of known binding activity was used. Some were

experimental and some were simulated (calculated). (See page 864, left column, under Results.) Different combinations of spectra were analyzed for their predictive ability. The spectra properties (peaks and intensities) are binned. (See page 862 under Computational Details.)


### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

npa  
April 26, 2002